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NOTICE OF ALLOWANCE AND FEE(S) DUE

48004 7590 01/27/2010

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CAPITAL CENTER, SUITE 1100
201 NORTH ILLINOIS STREET
INDIANAPOLIS, IN 46204-4220

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 01/27/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,176

04/13/2004

Jay A. Dittman

8627/219

3747

TITLE OF INVENTION: LARGE DIAMETER DELIVERY CATHETER/SHEATH

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	04/27/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

48004 7590 01/27/2010

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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,176 04/13/2004 Jay A. Dittman 8627/219 3747

TITLE OF INVENTION: LARGE DIAMETER DELIVERY CATHETER/SHEATH

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional NO \$1510 \$300 \$0 \$1810 04/27/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
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KOHARSKI, CHRISTOPHER 3763 604-523000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

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Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/823,176	04/13/2004	Jay A. Dittman	8627/219	3747
48004	7590	01/27/2010	EXAMINER	
BRINKS HOFER GILSON & LIONE/INDY/COOK BRINKS HOFER GILSON & LIONE CAPITAL CENTER, SUITE 1100 201 NORTH ILLINOIS STREET INDIANAPOLIS, IN 46204-4220			KOHARSKI, CHRISTOPHER	
			ART UNIT	PAPER NUMBER
			3763	
DATE MAILED: 01/27/2010				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 1229 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 1229 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/823,176	DITTMAN ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER D. KOHARSKI	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/12/2009.
2. ☒ The allowed claim(s) is/are 35-56.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Christopher D Koharski/
Examiner, Art Unit 3763

DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Larry A. Steward on 01/14/2010.

IN THE CLAIMS

Please amend the claims as follows:

1-34. **(Cancelled)**

35. **(new)** A sheath, comprising:

a lubricious inner tube having a passageway extending longitudinally therethrough, said passageway having a substantially uniform inner diameter of from 16 to 30 French, said inner tube having a wall thickness between about 0.001 and 0.01 inch (0.025 and 0.25 mm);

a coil having a plurality of coil turns extending longitudinally around a length of said inner tube, and a plurality of spacings between said turns, said spacings having a generally uniform width along said inner tube length; and

an outer tube positioned longitudinally around said coil and said inner tube and bonded to said inner tube through said spacings between said turns, said outer

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tube having a durometer of about 30 to 60 on the Shore D hardness scale, and having a wall thickness between about 0.004 and 0.014 inch (0.10 and 0.36 mm).

36. **(new)** The sheath of claim 35, further comprising a polymeric radiographic marker tube disposed between said inner tube and said outer tube adjacent a distal end of said coil.

37. **(new)** The sheath of claim 36, wherein said marker tube comprises a high density radiopaque material ranging between about 40 and 90 weight percent of the total weight of the marker tube.

38. **(new)** The sheath of claim 37, wherein said marker tube comprises nylon, and said radiopaque material comprises tungsten.

39. **(new)** The sheath of claim 36, wherein each of said outer tube and radiographic marker tube is formed of polyamide, wherein said uniform inner diameter , and each of said tubes has a durometer between about 35 and 50 on the Shore D scale.

40. **(new)** The sheath of claim 39, wherein each of said polyamide outer tube and radiographic marker tube has a durometer of about 40 on the Shore D scale.

41. **(new)** The sheath of claim 40, further comprising a side port distal of said flat wire coil, said side port extending through said inner tube, marker tube and outer tube.

42. **(new)** The sheath of claim 35, wherein said coil comprises flat wire.

43. **(new)** The sheath of claim 42, wherein said uniform width of said coil spacings is between about 0.004 and 0.08 inch (0.1 and 2 mm).

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44. **(new)** The sheath of claim 43, wherein said uniform width is about 0.012 inch (0.3 mm), and each coil turn of said coil has a width between about 0.005 and 0.030 inch (0.13 and 0.76 mm).

45. **(new)** The sheath of claim 44, wherein a proximal end of said coil is spaced from a proximal end of said sheath by about 0.5 to 5.0 inches (1.27 and 12.7 cm), and a distal end of said coil is spaced from a distal end of said sheath by about 0.1 to 2 inches (0.25 and 5.1 cm).

46. **(new)** The sheath of claim 45, wherein said proximal end of said coil is spaced from said proximal end of said sheath by about 1.2 inches (3.1 cm), and said distal end of said coil is spaced from said distal end of said sheath by about 0.8 inch (2 cm).

47. **(new)** The sheath of claim 35, wherein said uniform diameter of said passageway ranges from 18 to 24 French.

48. **(new)** The sheath of claim 35, wherein said uniform inner diameter of said passageway ranges from 20 to 26 French.

49. **(new)** The sheath of claim 48, wherein said uniform inner diameter of said passageway comprises one of 22 French and 24 French.

50. **(new)** The sheath of claim 48, further comprising a side port positioned at a distal end of said coil.

51. **(new)** The sheath of claim 35, wherein said outer tube has a durometer of about 35 to 50 on the Shore D hardness scale.

52. **(new)** The sheath of claim 51, wherein said outer tube durometer is about 40 on the Shore D hardness scale.

53. **(new)** The sheath of claim 35, wherein said inner tube comprises PTFE, said coil comprises stainless steel flat wire, and said outer tube comprises nylon, said outer tube having a durometer between about 35 and 50.

54. **(new)** The sheath of claim 36, wherein said radiographic marker tube is bonded to said outer tube by a thermal bond.

55. **(new)** The sheath of claim 54, further comprising a side port extending radially through said inner tube, said marker tube and said outer tube.

56. **(new)** The sheath of claim 36, wherein said radiographic marker tube and said outer tube are formed from the same polymer having the same durometer, and said tubes are bonded together by a thermal bond.

Allowable Subject Matter

Claims 35-56 are allowed over the prior art of record as filed in this office action.

The following is an examiner's statement of reasons for allowance: The claims in this application have been allowed because the prior art of record fails to disclose either singly or in combination the claimed device of a large diameter, flexible, kink-resistant, delivery catheter or sheath for percutaneous delivery of a contained and implantable medical device in the vasculature of a patient. The delivery catheter or sheath includes a reinforcement such as a flat wire coil with uniform spacing between the turns, which is compression fitted about an inner, lubricous PTFE tube. The delivery catheter or sheath further includes an outer tube of a heat formable polyamide material which is heat

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formed and compressed through the spaces between the turns of the wire coil to mechanically connect to a roughened outer surface of the inner tube. A polymeric radiopaque marker tube may be positioned at the distal end of the coil and between the inner and outer tubes for radiographic visualization.

The closest prior art of record is Parker (USPN5,700,253) and Lepulu et al. (USPN6,553,770), however these references do not disclose the device as claimed or described above.

Regarding claim 35, the closest prior art of record fails to teach among all the limitations or render obvious the specifics of sheath inner diameter sizing combined with the lower durometer outer tube and resultant assembly wall thickness.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 01/15/2010

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763